

# Safety and Efficacy of Medically Performed Tongue Piercing in People with Tetraplegia for Use with Tongue-Operated Assistive Technology

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**Background:** Individuals with high-level spinal cord injuries need effective ways to perform activities. **Objectives:** To develop and test a medically supervised tongue-piercing protocol and the wearing of a magnet-containing tongue barbell for use with the Tongue Drive System (TDS) in persons with tetraplegia. **Methods:** Volunteers with tetraplegia underwent initial screening sessions using a magnet glued on the tongue to activate and use the TDS. This was followed by tongue piercing, insertion of a standard barbell, a 4-week healing period, and an exchange of the standard barbell for a magnet-containing barbell. This was then used twice weekly for 6 to 8 weeks to perform computer tasks, drive a powered wheelchair, accomplish in-chair weight shifts, and dial a phone. Symptoms of intraoral dysfunction, change in tongue size following piercing, and subjective assessment of receiving and wearing a magnet-containing tongue barbell and its usability with the TDS were evaluated. **Results:** Twenty-one volunteers underwent initial trial sessions. Thirteen had their tongues pierced. One individual's barbell dislodged during healing resulting in tongue-tract closure. Twelve had the barbell exchanged for a magnet-containing barbell. One subject withdrew for unrelated issues. Eleven completed the TDS testing sessions and were able to complete the assigned tasks. No serious adverse events occurred related to wearing or using a tongue barbell to operate the TDS. **Conclusions:** Using careful selection criteria and a medically supervised piercing protocol, no excess risk was associated with tongue piercing and wearing a tongue barbell in people with tetraplegia. Participants were able to operate the TDS. **Key words:** assistive technology, plethysmography, spinal cord injury, tetraplegia, tongue drive system, tongue piercing

There are several assistive technologies (ATs) available or in development for people with disabilities, including those resulting from high-level spinal cord injuries (SCIs). These include sip-n-puff devices,<sup>1</sup> brain-computer interfaces,<sup>2,3</sup> head motion tracker,<sup>4</sup> head-array, eye tracker,<sup>5,6</sup> speech recognition systems,<sup>7</sup> and electromyographic-controlled devices.<sup>8,9</sup> Sip-n-puff systems are relatively low cost, simply

designed, and easy to use. However, they require an effective level of diaphragm control and continuous cleaning/maintenance. Electroencephalography-based brain-computer interfaces are slow and take substantial time to set up. They require specialized training to use and constant attention by the user. They have limited flexibility and high error rates. Facial electromyography electrodes are aesthetically challenging. Systems that use sensors

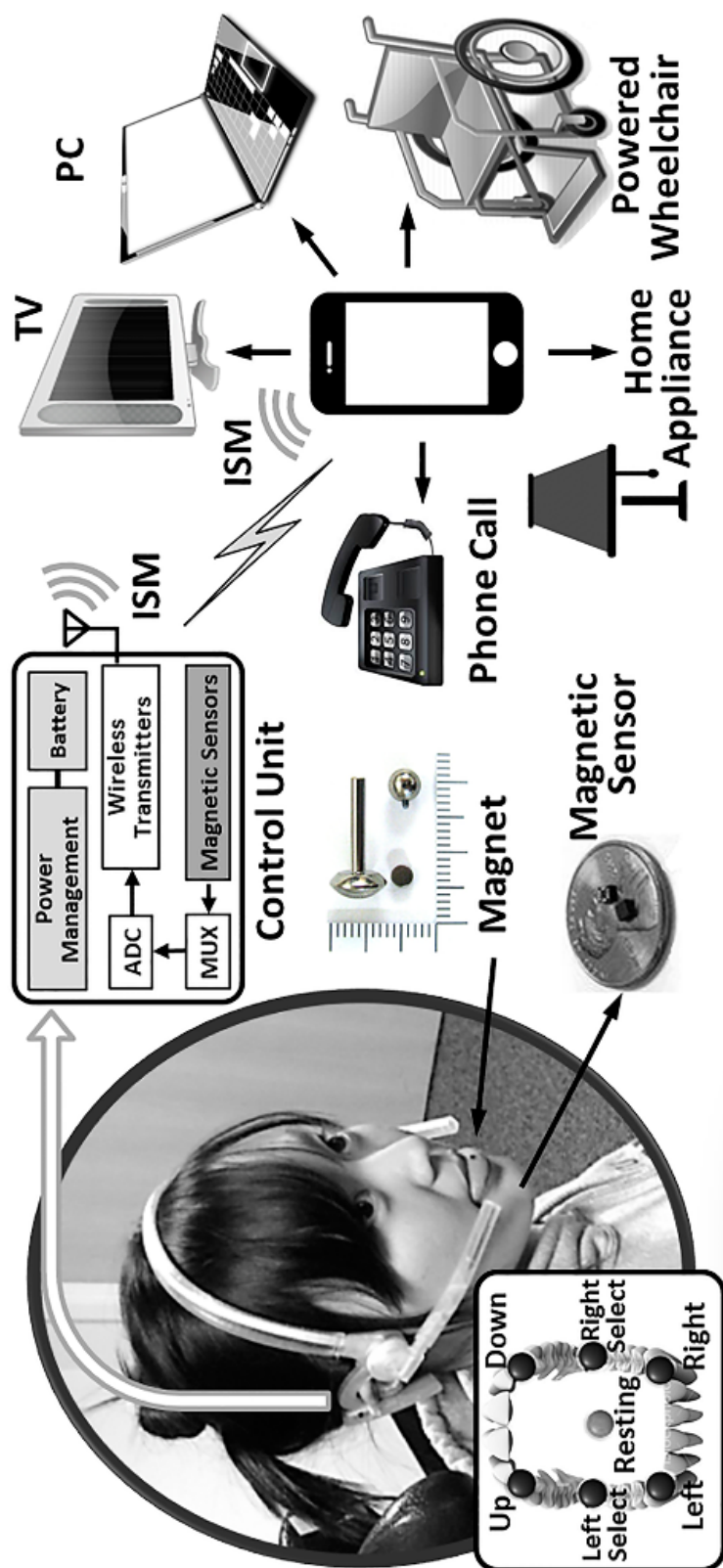
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**Figure 1.** The tongue drive system consists of a magnetic tracer attached to the tongue, a headset with an array of magnetic sensors, a control unit, and a smartphone with wireless receiver. Using a graphic user interface on a computer screen, initially, the participant trains the system to recognize 6 tongue positions. These may be individually defined by the user but suggested positions are: root of the fourth bottom tooth on the left as the LEFT command; root of the fourth bottom tooth on the right as the RIGHT command; root of the fourth top tooth on the left as the UP command; root of the fourth top tooth on the right as the DOWN command; last upper left tooth/left cheek as the LEFT-SELECT command; last upper right tooth/right cheek as the RIGHT-SELECT command. The sensors detect the changes in the magnetic field due to the position of the tracer inside the user's mouth. The control unit sends that signal wirelessly to a smartphone, which processes the signal into a predetermined user defined function, such as moving a mouse cursor on a computer screen, dialing a phone number, driving a powered wheelchair, or turning lights on or off.

on the neck muscles, head motion trackers, or a head-array require head movement capability. They are tiring and not optimal for long-term use. Eye trackers need a camera in front of the face. This blocks the user's visual field. They are susceptible to ambient light variations and may be unsafe for wheelchair use. Speech recognition software is efficient for typing, but is less useful for navigating a computer cursor or a wheelchair.

A recently described AT, called the Tongue Drive System (TDS), uses tongue movement for activation.<sup>10,11</sup> The human tongue can move rapidly and accurately such that the tip can touch every tooth.<sup>12-15</sup> The direct connection between the brain and tongue generally remains intact even after high-level SCIs.

The TDS consists of a disc-shaped 5 x 1 mm, or smaller, magnet attached to the tongue. Tongue movements induce magnetic field changes that are detected by sensor arrays and sent wirelessly to a computer interface that translates each movement into a specific user-defined function such as operating a computer, dialing a phone, or driving a powered wheelchair (PWC) (**Figure 1**).

Gluing the magnet to the tongue using dental adhesive has been successful for short-term TDS usage,<sup>13,16</sup> but long-term use requires semi-permanent attachment of the magnet. We have previously designed a tongue-piercing protocol that is performed in a medical setting by medical personnel on able-bodied individuals and confirmed that a magnet-containing barbell inserted through the tongue works for control of the TDS.<sup>17-20</sup> These individuals each wore a magnet-containing barbell for about 2 months while participating in weekly TDS testing sessions. The theoretical concern for interaction with stainless steel flatware proved not to be a problem.

Tongue piercing, defined as the insertion of a sharp object through the tongue, has a long history as a form of religious and cultural symbolism. There are no reliable general population prevalence data on pierced tongues, however intraoral piercing has general population rates of up to 5% in US adults under 50 years of age<sup>21</sup> and 6.5% in those aged 16 to 24 years in England.<sup>22</sup> Most intraoral piercings are not done by medically trained professionals.<sup>23-25</sup> Common early complications include tongue

swelling, pain, bleeding,<sup>26,27</sup> difficulty eating, difficulty speaking, and excessive salivation.<sup>28,29</sup> Infections after piercing, both at the piercing and remote sites, are a concern.<sup>30</sup> There are no data related to the performance of tongue piercing in people with SCI.

The intent of the current study was to test the safety of the same tongue-piercing protocol in people with tetraplegia and to evaluate their acceptance of wearing a magnet-containing barbell for use with the TDS.

## Methods

This multicenter study included Georgia Institute of Technology and Shepherd Center in Atlanta, Georgia, as well as Northwestern University in Chicago, Illinois. The study was approved by the institutional review board of record for each institution. Participants were recruited by word of mouth, flyers, and print media advertisements. Signed, written, or witnessed verbal consent was obtained. Adult volunteers (age 18-65 years) with mobility limitations requiring a PWC and limited upper limb strength were included. Those with a predisposition to infection, bleeding, or factors that might prevent the use of the TDS, such as vision/hearing deficiencies, inability to sit for 4 hours even with pressure relief, or inappropriate intraoral anatomy (eg, a short lingual frenulum limiting anterior tongue movement), were excluded.

## Procedures

To ensure sufficient physical and cognitive ability to perform TDS tasks, each participant underwent trial sessions using the system with a magnet glued to the dorsal surface of the tongue with dental adhesive. These magnets were surrounded by a medical grade epoxy/silicone combination with an embedded 10-in. length of dental floss attached to the TDS headset to prevent aspiration in case of magnet tongue separation. Those who successfully completed the trial sessions were scheduled for admission to the Shepherd Center or the Clinical Research Unit (CRU) at Northwestern University for tongue piercing. Participants were instructed



**Figure 2.** Measuring the thickness of a tongue with a Boley gauge.

to stop taking any aspirin-containing products for 1 week and nonsteroidal anti-inflammatory agents for the appropriate medication-specific washout period prior to the piercing.

On admission, additional history was taken and a physical examination performed, with attention to health issues that would increase the participant's risk for piercing complications or prevent advancement to further TDS testing sessions (eg, pressure ulcers that reduced sitting capacity). Vital signs were recorded. The tongue was photographed in relaxed and firm states from the top, bottom, left, and right. Baseline width and thickness of the tongue (at the location of the anticipated piercing tract) were measured using a caliper type instrument, called a Boley gauge (**Figure 2**). Intraoral volumes were measured using a novel technique, called oral plethysmography, in which the oral cavity was filled with water; the water was then spit into a measuring cup and the volume read. This was done 5 times and the average of the 5 readings was taken as the intraoral volume.<sup>31</sup> Chlorhexidine gluconate 0.12% mouthwash was used to clean the mouth.

Each participant was transferred to a hospital bed and the bed head was elevated to 30 to 45 degrees. The tongue was grasped gently with a Foerster sponge clamp and pierced by a physician using a 12-gauge hollow bore piercing needle that was passed dorso-ventrally through the tongue. At the same time, a cork was held under the tongue so that the sharp inferior tip of the needle was immediately embedded into the cork (**Figure 3**).<sup>18,32</sup> The shaft of an internally threaded titanium barbell with the dorsal ball welded to the shaft was aligned with the blunt end of the piercing needle and, using the barbell, the piercing needle was pushed all the way through the tongue so that the needle and cork dropped into a beaker below. The inferior barbell ball was screwed on tightly, and the clamp was removed. In 7 individuals, this was done without anesthesia; in 5 participants, 1.5 to 3 cc bupivacaine 0.5% with 1:200,000 epinephrine was injected along and around the anticipated piercing tract prior to piercing.

The location of the piercing tract was in the midline just anterior to the insertion of the frenulum on the inferior surface of the tongue.



**Figure 3.** Piercing the tongue. Tongue held with Foerster tissue clamp. Position of needle insertion marked with a surgical tissue marker. Piercing needle inserted through the tongue with point embedded in a cork inferiorly. Beaker below ready to catch the cork and needle as they fall.

This was to avoid discomfort and bruising from the inferior ball of the barbell rubbing on the frenulum, at the same time attempting to prevent the increased risk of tooth, gum, and bone damage; speech impairment; and avulsion injury related to a more anterior position.<sup>33-39</sup> This was done despite the fact that more distal placement of the magnet on the tongue would have resulted in its greater mobility, possibly making it easier to hit assigned targets within the mouth for operation of the TDS.

The participants and caregivers/nurses received both oral and written aftercare instructions (see box, “Tongue Piercing Aftercare Instructions”). Vital signs were recorded immediately following the procedure, every 4 hours on the day of the procedure, and every 8 hours for the duration of the hospital stay.

The first 9 participants remained in the hospital for 72 hours after the piercing. Four participants who entered the study later were discharged within 24 hours, due to the absence of postprocedure complications among the early participants. For safety reasons, if the participant was released earlier than 72 hours, 1 or 2 additional visits were

scheduled during the second and third days after the procedure.

Pain was assessed using a 0 to 10 scale. Using a 4-point severity scale (none, mild, moderate, and severe), 10 additional self-reported symptoms were assessed: bleeding, swelling, difficulty swallowing, difficulty eating, difficulty speaking, drooling, numbness, headache, flushing, and dizziness. Subjective symptoms were recorded, tongue-piercing sites were photographed, and Boley gauge and oral plethysmography measurements were taken on postprocedure days 1, 2, and 3. Oral care continued at home with a change to a nonalcoholic antiplaque mouthwash after day 7, as prolonged use of chlorhexidine may discolor teeth.

After 4 weeks, when the anticipated tongue swelling and inflammation had subsided, the long temporary barbell was removed and examined for its condition. It was replaced by a shorter, purpose-made, internally threaded titanium barbell with a boron, iron, and niobium magnet completely encased in the dorsal ball, which was welded onto the shaft. A standard piercing stainless steel taper was used to facilitate this exchange. Again,

### Tongue Piercing Aftercare Instructions

#### Care for your pierced tongue

- Brush teeth with soft brush and toothpaste after each meal and before bed.
- Rinse mouth with chlorhexidine antibacterial mouthwash after each meal and before bed.
- Gently paint jewelry with brush dipped in chlorhexidine antibacterial mouthwash after each meal and before bed.
- **After 1 week, stop using the chlorhexidine mouthwash and use an alcohol-free antiplaque formula mouthwash to rinse the mouth and clean jewelry.**
- To prevent plaque formation and ensure the ability to remove the barbell when necessary, continue the above care for as long as you wear piercing jewelry.

#### Things to do:

- REST YOUR TONGUE.
- To minimize pain and swelling, sip cold water or suck on chipped or shaved ice.
- For additional pain control, take oral acetaminophen as needed.
- Eat slowly and take small bites.
- Place bites of solid food between molars to avoid using your tongue.
- Eat cold, soft foods such as smoothies, shakes, and ice cream.
- Properly wash hands before touching jewelry and surrounding area.
- **Check the security of your jewelry each night by checking the ball on the underside of your tongue: loosen and then tighten it. This is important to ensure the ability to remove the barbell in case of need and to prevent inhalation or swallowing of any part of the jewelry.**

#### Things NOT to do:

For the first 2 days:

- Do not stretch or bend your tongue.
- Talk as little as possible.

For the first 7 days:

- No anti-inflammatory medications such as ibuprofen, naproxen, or aspirin
- No foods that are sticky in the mouth such as gum, candy, peanut butter, mashed potatoes, oatmeal
- No salty, spicy, acidic or hot foods and beverages
- No sucking on straws

For the first 4 weeks:

- No smoking or chewing tobacco
- No dental work
- No tongue kissing or oral sexual contact even with barrier protection

For the duration of wearing piercing jewelry:

- Do not rotate or play with tongue jewelry.
- Do not use harsh or alcohol-containing mouthwash.
- Do not chew on hard objects, eg, pens, utensils, sunglasses, fingernails.

tongue photographs and Boley gauge and oral plethysmography measurements were taken.

Over the next 5 to 8 weeks, participants took part in 6 testing sessions, each divided into two 4- to 6-hour segments. In the first segment, each participant used his or her magnetic tongue barbell to perform computer tasks. In the second segment, the barbell was used to drive a PWC through

an obstacle course, activate in-chair weight management via power seating, and operate a phone. Each task was repeated 3 times, and the ability of the participants to perform each task was evaluated using speed and accuracy measures depending on the task.<sup>11,19,20,40</sup> For instance, Fitts' law was applied to evaluate computer access tasks, such as center-out tapping. This task consisted

of 48 targets with 3 widths (30, 61, and 122 pixels) along cardinal and ordinal directions at 3 distances (61, 122, and 244 pixels). Each trial used 16 of the 48 targets. Participants tried to hit the targets as speedily and accurately as possible. The main measure was the amount of information delivered within a second to the computer (ie, throughput in bits per second). Throughput is a ratio between the index of difficulty of each target and the movement time to reach the target.<sup>20</sup> PWC navigation included driving through a ~50-meter course that included 6 turns and 24 obstacles using 3 control strategies: unlatched, latched, and semi-proportional.<sup>19</sup> Completion time and the number of navigation errors (ie, the hitting of obstacles and driving outside the track) were recorded.

The magnet-containing barbell stayed in place for the duration of the study, but the TDS was not available for use between sessions. After the last session, subjective impressions about the tongue-piercing experience, the wearing of the magnet-containing barbell, and its efficacy in operating the TDS were solicited using a questionnaire (**Appendix**). The barbell was removed, and each individual had the option to insert alternative tongue jewelry or let the tract close.

## Results

Twenty-one participants were enrolled and completed the initial trial sessions. Eight were disqualified for inability to operate the TDS during the preliminary trial (2), unrelated medical issues that arose after consent (3), or failure to comply with study visits (3). Thirteen participants (male 11, female 2; median age, 37 years; age range, 27–56 years) had their tongues pierced (**Table 1**). No study-related serious adverse events occurred during the initial trial sessions or the piercing procedures. One participant was removed from the study during recovery because the barbell came out and was not re-inserted prior to tongue-tract closure. Six of the 12 remaining participants reported pain and tongue swelling, and 4 had some difficulty speaking and eating during the first 3 days after piercing (**Figure 4**), correlating with oral plethysmography and Boley gauge confirmation

of an approximate 17% increase in tongue size between days 1 and 2 (**Figure 5**).

On 3 occasions during the initial 4-week healing period, it was necessary to remove barbells temporarily for unrelated medically indicated interventions. One participant underwent electrohydraulic lithotripsy for renal stones. As there was concern for continued patency of the tract during the procedure, microbore tubing was inserted, using a taper as a guide. The ends were tied in a loose loop throughout the procedure and the barbell was reinserted immediately after without complication.<sup>41</sup> The same individual, as well as a second participant, required magnetic resonance imaging, again for unrelated medical issues. No retainers could be used as there was concern for overheating.<sup>42</sup> The barbells were removed prior to imaging and were reinserted using a taper immediately afterwards.

Twelve participants (11 with American Spinal Injury Association Impairment Scale [AIS] of A and 1 with AIS of B) completed the barbell exchange, at which time each barbell was found to be meticulously clean (**Figure 6**). One man withdrew from participation after this due to unrelated social issues.

Eleven participants completed at least 3 sessions and 8 of 11 participants completed all 6 testing sessions using the TDS. Six participants were routine sip-n-puff users and the other 5 were joystick users. SCI levels were between C2 and C6. Postinjury duration was 3 to 21 years (median 12). One participant required ongoing ventilator support. No serious adverse events occurred in relation to wearing the barbell or the tongue movements required to operate the TDS.

## Subjective reactions

Two participants complained of tongue fatigue after the initial testing session only. An additional 2 complained of tongue fatigue after 4 of the 6 testing sessions. These individuals had used a sip-n-puff device immediately prior to the sessions. All 4 continued testing sessions to the completion of the whole protocol.

Study questionnaire data gathered from questions requiring a yes or no answer revealed

**Table 1.** Participant demographics

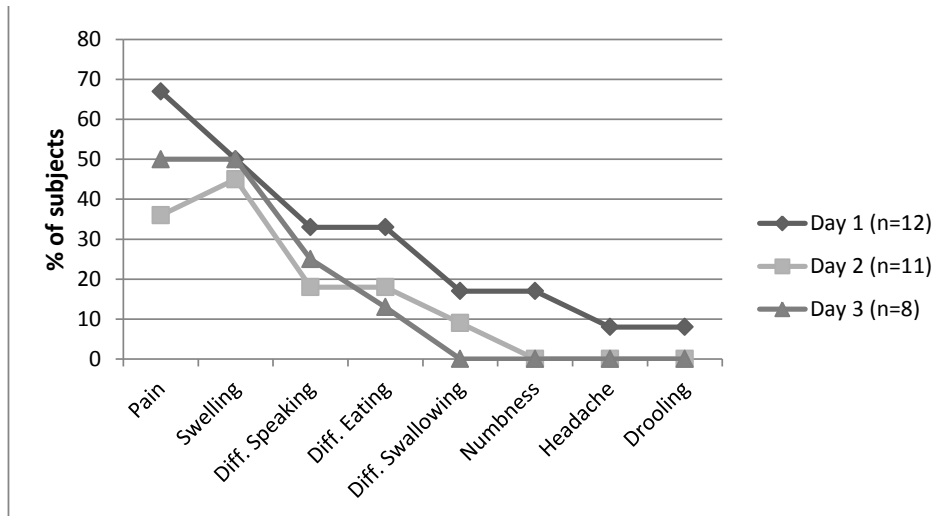
Participant	Age, years	Sex	Ethnicity	Educational status	AIS	ISNCSCI motor level	Years since injury	Time in hospital, hours
1	34	F	African American	High school graduate	A	C5	12	72
2	37	M	Hispanic	2 years high school	A	C6	19	72
3	29	M	White	2 years high school	A	C5	12	72
4 <sup>a</sup>	41	M	African-American	High school graduate	A	C5	9	72
5 <sup>b</sup>	42	M	Hispanic	Completed high school	A	C5	16	72
6	37	M	White	College	A	C4	5	72
7	53	M	White	Some high school	A	C5	4	72
8	34	M	African American	Started 12th grade	A	C4	11	72
9	47	M	White	1st quarter of college	B	C3	21	72
10	27	M	African American	Some high school	A	C5	7	24
11	56	F	African American	2 years junior college (medical assistant)	A	C5	14	24
12	29	M	Hispanic	Some high school	A	C2	3	24
13	46	M	Hispanic	College	A	C4	1	24

Note: AIS = American Spinal Injury Association Impairment Scale; ISNCSCI = International Standards for Neurological Classification of Spinal Cord Injury; SNP = sip-n-puff.

<sup>a</sup>Participant 4: Left study at the end of week 4.

<sup>b</sup>Participant 5: Excluded related to loss of the tongue barbell within the first 48 hours.





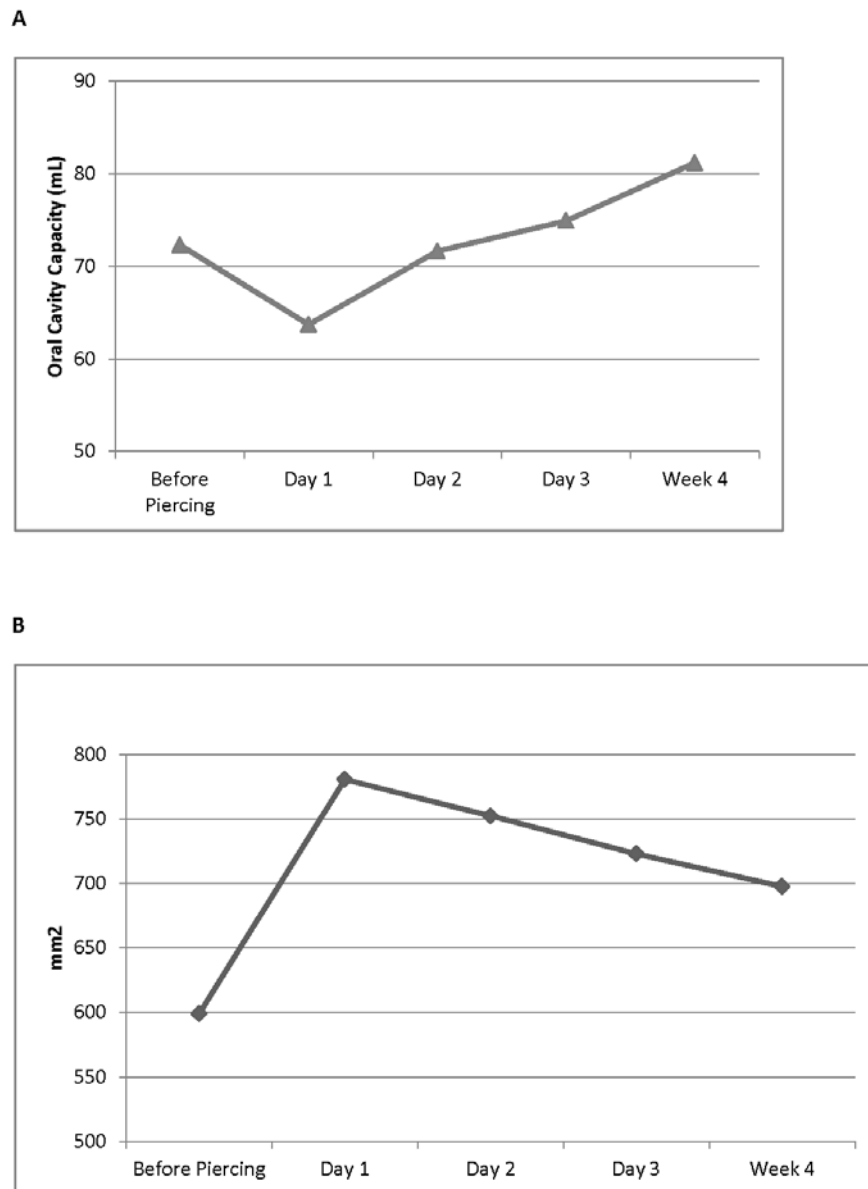
**Figure 4.** Symptoms reported on days 1-3 after piercing. Although also specifically asked, no subject complained of bleeding, flushing, or dizziness. Diff = difficulty.

that 2 of 11 participants said their tongues were tired at the end of each session, a different person (1/11) said his jaw was tired, and 2 others said their shoulders were tired. These latter included 1 individual who also said his neck was tired. In answer to the question “Did any other part of the body feel tired?”, 1 individual commented that his “brain was tired” and a second individual that his “eyes were tired.” Nine participants did not like the appearance of the headgear, but only 3 were concerned about how it looked to others. Ten said the magnet-containing barbell was comfortable. The person who said it was uncomfortable commented that the bottom of the tongue stayed sore. Six people said the tongue barbell moved while using the TDS, but no one commented that this made the TDS difficult to use. One person said he got specific comments from others about the tongue barbell, but he did not say what they were. Six were going to keep wearing tongue jewelry after the end of the study, 4 were not, and 1 was undecided.

Study questionnaire data, based on a 5-point scale, revealed that in 3 participants, the tongue piercing went unnoticed by others. In another 7, it generated a positive reaction; in 1, the reaction was somewhat negative. Although none of the participants were concerned about how the barbell

looked to others, 4 were very concerned about the appearance of the head gear. Two participants had found the tongue-piercing experience moderately painful while another 2 had found it very painful, although the majority (10/11) said the tongue piercing experience was not a big deal. The person who said it was moderately difficult also found it very painful; this was the same person who found it more painful and difficult than expected. However, 8 did not find it as painful as they had expected and 2 felt it was much as they had expected. All subjects felt the piercing aftercare instructions (see box, “Tongue Piercing Aftercare Instructions”) were clear.

All participants said the TDS was effective or very effective for using the computer, driving a PWC, dialing phone numbers, and doing in-chair weight shifting. All but 1 said it was about the same or easier to use as well as similarly effective or more effective than their current device. The answer to the overarching question about getting a tongue piercing, wearing a magnetic tongue barbell, and using the TDS revealed that 10 were more than satisfied with the system and 1 person was indifferent. Eight participants said they would be willing to keep wearing a tongue piercing in order to use the TDS, 1 said “maybe,” and 2 said they would not.



**Figure 5.** Tongue swelling. **(A)** Oral plethysmography. **(B)** Calculated tongue cross-sectional area using Boley gauge depth and width measurements. mL = milliliters; mm = millimeters.

## Discussion

As in the previous proof-of-concept tongue-piercing study performed in able-bodied individuals,<sup>17</sup> individuals with SCI experienced only limited early postpiercing tongue swelling, eating, speaking difficulties, and pain. The limited swelling was confirmed by plethysmography and Boley gauge measurements. The increased

plethysmography measured and calculated intraoral volume at week 4 was probably related to the learning process of both the researchers and the participants (**Figure 5A**). The larger tongue cross-sectional area at week 4 is in part attributable to the presence of the barbell in the tongue (**Figure 5B**).

As an adaptation for people with tetraplegia, early participants were kept under observation at

the Shepherd Center or CRU for 72 hours following the piercing procedure. This was because of the inherent risks of tongue piercing and the special needs of individuals with tetraplegia. Partway through the study, the protocol was modified to allow for shorter inpatient stays at the discretion of the supervising physician. This decision was based on the absence of serious adverse events from the piercing procedure itself and the desire to limit the disruption of participants' established routines. We attribute the limited symptoms to vigilant and involved caretakers who ensured security of the tongue barbells and maintained meticulous oral hygiene. Much of this resulted from paying attention to the specific aftercare instructions.

In general, tongue piercing is so rapid a procedure that pain at the time is negligible.<sup>43</sup> In this study, early reports of pain were variable and short-lived. It is probable that the use of local anesthetic did reduce discomfort, and it is likely that the concomitant use of the vasoconstricting agent minimized the risk of serious bleeding. However, probably more important was the avoidance of aspirin and nonsteroidal anti-inflammatory agents during the perioperative period, as well as the strict adherence to the specific aftercare instructions.

All barbells were 12-gauge, a size commonly used for this purpose. Initial barbells were approximately one-quarter of an inch longer than the measured depth of the tongue to allow for swelling. It is standard practice to wait 4 weeks to replace the initial barbell with a more snug-fitting one.<sup>44</sup>

Sensitization to nickel is common.<sup>45</sup> Titanium rarely causes sensitization, which is why titanium barbells were used. Barbells were internally threaded as external threading is likely to tear any tissue through which it passes.

Some procedures, such as magnetic resonance imaging or intubation for anesthesia, require that all materials be removed. The need for these interventions is frequent among people with tetraplegia. This issue was addressed by the temporary removal of the barbell. The use of 12-gauge microbore tubing proved effective to maintain tract patency.<sup>41</sup> Burns may occur during electrocautery or cardiac defibrillation, so decisions as to whether to place a tract patency retainer must be made on a case-by-case basis.<sup>46,47</sup> In addition,

imaging procedures may need position adjustment in order to visualize an area of interest.<sup>48</sup>

Using careful participant selection and a medically supervised piercing protocol, no excess risk was associated with tongue piercing and the wearing of a tongue barbell in people with tetraplegia compared with able-bodied individuals in the medium term.<sup>49</sup> Autonomic dysreflexia was not expected because the piercing was performed above the level of injury and there are no physical reasons why the tongues of persons with tetraplegia should react differently than those of able-bodied persons. Initial concerns focused on whether people with tetraplegia would have increased risk of infection or aspiration due to their dependence on others for oral hygiene and tightening of the jewelry. Instead, the shiny barbells after 4 weeks of wear, compared with the heavy plaque accumulation noted during the proof-of-concept study, suggested more assiduous care than that done by able-bodied individuals (**Figure 6**). This is reassuring as it is important that removal of a tongue barbell be easy in case of emergency. In this study, the dorsal magnet-containing balls were welded on to the shafts so that the only means of removing the barbell from the tongue involved unscrewing the inferior ball.

All participants reported that the TDS controlled using an inserted magnet-containing tongue barbell was effective for performing the tasks presented and that it was at least as or more effective than their current control device. It was also as easy as or easier to use than their current control device. It is interesting that even though the majority did not like the appearance of the headset, they were not worried about how it or wearing a tongue barbell looked to others. In the future, to dispense with the headset, it may be possible to embed the control unit in an intraoral brace placed external to the lower gum in similar fashion to an orthodontic retainer. At the same time, it is likely that any perceived social stigma related to the wearing of a tongue barbell would become even more irrelevant if tongue piercing were to become a medically acceptable procedure enabling AT. The problems of tongue, jaw, neck, shoulder, eye, and even brain fatigue might become less with time. The testing

**A****B**

**Figure 6.** (A) Barbell at 4-week exchange from an able-bodied individual. Plaque on the inferior ball (picture taken during similar previous study of able-bodied individuals). (B) Barbell at 4-week exchange from an individual with tetraplegia. Shiny inferior ball.

sessions occurred several days apart and required significant, often disruptive, travel to the testing sites, as well as recalibrating and relearning the system at each session. Learning occurred early in this study; if a person with tetraplegia were to have the TDS constantly available, it is likely that learning would continue to a higher plateau and the physical aspects of the involved muscles would become stronger.

The purpose of this article is to show that tongue piercing is doable and safe in the medium term in people with tetraplegia. This article also shows that the TDS was accepted by the participants and, in predetermined activities, was used to complete tasks with acceptable speed and accuracy.

### Limitations

Only participants with high-level SCIs were enrolled, so findings cannot be generalized to people with other neurological disorders. Due to tight inclusion/exclusion criteria, there were

only a small number of participants. An obstacle to recruitment was the unwillingness of some individuals to receive tongue piercing. This may have been due to the fact that the TDS was available only for use during the 12 weeks of study participation. This may have contributed to the split questionnaire responses regarding willingness to maintain a tongue piercing for future use with the TDS.

Eight participants completed the questionnaire immediately after the final session, while 3 completed the questionnaire at some time after an interim session. Accuracy of recall may have been affected by the length of exposure as well as by the variable time lapse between the conclusion of the trial and being asked about it.

### Conclusions

A medically performed tongue-piercing method has been developed and tested for use with the TDS by people with high-level SCIs. Compared with

able-bodied persons, there was no increased risk associated with tongue piercing and the wearing of a tongue barbell in the medium term. People with tetraplegia were able to use the TDS for computer access, PWC control, phone dialing, and in-chair weight shifting.

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**ClinicalTrials.gov identifier:** NCT01124292

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## APPENDIX

### Questionnaire About the Tongue Piercing Experience

Questions requiring “yes” or “no” answers with space for an explanation:

At the end of each session:

- Was your tongue tired? Was your jaw tired? Was your neck tired? Were your shoulders tired?
- At the end of each session, did any other part of your body feel tired?
- Was the headgear comfortable? Did the headgear move on your head while you were using the Tongue Drive System (TDS)?
- Did you like the appearance of the headgear? Were you concerned how it looked to others?
- Was the magnetic tongue stud comfortable?
- Was it loose so that it moved on your tongue while you were using the TDS?
- Did anyone make specific comments about your tongue stud?
- Are you going to keep wearing jewelry on your tongue?

#### Questions requiring answers on a 1 to 5 scale:

How did other people react to your tongue stud?				
Negative	Somewhat negative	Did not notice it	Somewhat positive	Positive
1	2	3	4	5
Was the TDS effective for using the computer?				
Was the TDS effective for driving the wheelchair?				
Was the TDS-iPod effective for dialing phone numbers?				
Was the TDS effective in weight shifting?				
Completely ineffective				Very effective
1	2	3	4	5
Overall, the TDS was:				
Very difficult to use		OK		Very easy to use
1	2	3	4	5
How was your tongue piercing experience?				
Very difficult	Significantly	Moderately	A little	Not a big deal
Very painful	Significantly	Moderately	A little	Not painful
1	2	3	4	5
Was your tongue-piercing experience more painful or difficult than you expected?				
Very much so		About the same as I expected		Not very
1	2	3	4	5

(Continued)

**Questions requiring answers on a 1 to 5 scale: (Continued)**

How clear were the instructions you were given after tongue piercing?				
Not at all clear	Not clear	Neither clear or unclear	Somewhat clear	Very clear
1	2	3	4	5
Would you be willing to keep wearing a tongue piercing in order to use the TDS?				
No thanks!	Most likely no	Maybe	Most like yes	Yes, of course
1	2	3	4	5
Compared to your current assistive device, the TDS was:				
More difficult to use	Somewhat more difficult	About the same	Somewhat easier	Much easier to use
1	2	3	4	5
Compared to your current assistive device, the TDS was:				
Not as effective	Somewhat less effective	About the same	Somewhat more effective	More effective
1	2	3	4	5
How concerned were you about how the tongue stud looked to others?				
How worried were you about how the headgear looked to others?				
Very concerned	Significantly concerned	Moderately concerned	A little concerned	Not at all concerned
1	2	3	4	5
Now that you have had a tongue piercing, a magnetic-tongue stud, and used the TDS for a few weeks, how satisfied are you with this system?				
Not at all satisfied	Not satisfied	Neither satisfied nor dissatisfied	Somewhat satisfied	Very satisfied
1	2	3	4	5